UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE KERYX BIOPHARMACEUTICALS, INC., SECURITIES LITIGATION	Civil Action No. 13-cv-00755 (KBF)

LEAD PLAINTIFF'S MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS CONSOLIDATED AMENDED COMPLAINT

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Lead Plaintiff David A. Wilkinson ("Plaintiff") respectfully submits this Memorandum of Law in opposition to Defendants'[1] Motion to Dismiss Plaintiff's Consolidated Amended Complaint (the "CAC").

I. Preliminary Statement

Defendants ask the Court to rubber-stamp their motion to dismiss this case based upon the holding in *Abely v. Aeterna Zentaris Inc.*, No. 12 Civ. 4711 (PKC), 2013 WL 2399869 (S.D.N.Y. May 29, 2013) ("*Aeterna*"). Rather than address Plaintiff's well-pleaded allegations directly, Defendants draw incorrect and flawed comparisons between the CAC and the *Aeterna* complaint, disregarding the key ways in which the detailed allegations set forth in the CAC distinguish this case from *Aeterna*. Such arguments are unavailing, as the pleading deficiencies warranting the complaint's dismissal in *Aeterna* are simply not present here. Indeed, the Court's independent review of the CAC will undoubtedly show that Plaintiff has adequately alleged violations of the federal securities laws by Defendants.

In particular, Plaintiff alleges that between June 1, 2009 and April 1, 2012, inclusive (the "Class Period"), Defendants represented to investors that Phase 2 of the Company's clinical trial testing the efficacy of the drug perifosine in the treatment of metastatic colorectal cancer ("mCRC") generated "statistically significant" results. Based upon these results, which "demonstrated" perifosine's "clinical benefit," Defendants further assured investors that they could expect a successful outcome in Phase 3 of the clinical trial. However, Defendants' statements touting perifosine's purportedly positive Phase 2 results were materially misleading because Defendants omitted critical details relating to the design of Keryx's Phase 2 study and the Company's statistical analysis – material information that reasonable investors needed in

[1] Defendants are Keryx Biopharmaceuticals, Inc. ("Keryx" or the "Company") and Ronald Bentsur ("Bentsur") (collectively, "Defendants").

order to have a full and accurate understanding of Keryx's statistical findings. Specifically, Defendants did not tell investors that (1) Keryx had interposed multiple factors into the Phase 2 study that are known to have a direct and material impact on the statistical analysis of clinical trial data, but that (2) in contravention of unequivocal guidance released by the U.S. Food and Drug Administration ("FDA"), other regulatory bodies, and industry standards, the Company did not adjust the P-values applied in the statistical analysis of the Phase 2 study results to account for such factors.

In response to these particularized allegations, Defendants argue that Plaintiff fails to plead falsity because, like the *Aeterna* plaintiff, Plaintiff "merely disagrees" with the design and methodology of Keryx's clinical trial. This argument is demonstrably incorrect, as the false and materially misleading statements alleged in the CAC do *not* attack the design and methodology of Keryx's clinical trial, but instead challenge Defendants' specific disclosures that provided an incomplete and misleading impression of what steps Defendants took in the Phase 2 trial, and therefore, what basis they had to conclude and announce that the Phase 2 results were "statistically significant."

Plaintiff further alleges scienter with the requisite particularity. In response, Defendants launch a wide-ranging, boilerplate attack on the CAC's scienter allegations, arguing that Plaintiff fails to show scienter because: (1) the CAC's allegations are conclusory and speculative; (2) Plaintiff's motive and opportunity allegations are insufficient; and (3) Plaintiff does not show conscious misbehavior or recklessness because the CAC fails to allege that Defendants intentionally applied an improper statistical analysis. All of these arguments fail because the CAC pleads with particularity that Defendants controlled the Phase 2 trial and recklessly made misleading half-truths and omitted material facts that they knew regarding the statistical analysis

of the perifosine Phase 2 results. Nothing more is needed to meet the pleading standard for scienter, and Defendants' motive and opportunity arguments are of no consequence.

In addition, Plaintiff properly pleads loss causation. Defendants erroneously contend that the CAC fails to allege a corrective disclosure, and that the CAC fails to plead loss causation under a materialization of the risk theory. First, the CAC clearly alleges a partial collective disclosure on October 19, 2011, when the public first became aware through a news article that the highly touted Phase 2 efficacy results may not have been statistically significant, and the price of the stock dropped by 6%. After Defendants glossed over this disclosure, continued to tout the "highly statistically significant" efficacy results from the Phase 2 perifosine study, and failed to disclose the additional information necessary for the market to determine the extent of the statistical distortions involved in Phase 2, a "materialization of the risk" concealed by Defendants – that there was no statistically-based rationale for advancing to a Phase 3 perifosine trial – occurred at the end of the Class Period when Defendants ultimately disclosed the failure of perifosine to demonstrate efficacy in the broader Phase 3 trial. Thus, Defendants' arguments with respect to loss causation fail on all fronts.

Finally, contrary to Defendants' contention, the CAC states a claim under Section 20(a) because it establishes Defendants' primary liability under Section 10(b).

In sum, the CAC, which is materially distinct from the *Aeterna* complaint, sufficiently pleads Defendants' violations of the federal securities laws, and Defendants' motion to dismiss should be denied in all respects.

II. Statement Of Facts

A. Overview of FDA Guidance And Industry Standards Regarding Statistical Analyses In Clinical Trials

Statistical analyses in clinical trials commonly use data points known as "P-values," which represent the probability of observing a result by chance alone, to assess the statistical significance of a clinical trial's results. ¶ 33.[2] P-values are thus a key component in determining the efficacy of a particular drug treatment. Indeed, to prevent the mistaken claim that an ineffective drug treatment is beneficial, the FDA has issued guidance recommending that appropriate adjustments to P-values be made to account for the presence of factors with the potential to distort an evaluation of statistical significance in clinical trials. *See* ¶¶ 37-41, 43-49. As relevant to this case, these factors include: (1) **unplanned interim analyses**, (2) **multiplicity**, and (3) **hypothesis generation**.

Regarding unplanned interim analyses, FDA guidance states, "[r]evisions not previously planned and made or proposed after an unblinded interim analysis ***raise major concerns about study integrity*** (*i.e.*, potential introduction of bias)."[3] ¶ 46 (citing FDA Guidance for Industry: Adaptive Design Clinical Trials for Drugs and Biologies, Draft Guidance, Lines 86-88 (February 2010) ("FDA Draft Guidance")). Specifically, the FDA recognizes that such unplanned revisions "might increase the potential for a statistically successful final study result," which "will usually create difficulty in controlling the Type I error rate and difficulty in interpreting the study results." ¶¶ 47-48 (quoting FDA Draft Guidance at Lines 547-51). The FDA therefore advises that unplanned interim analyses "***should be avoided***." ¶ 45 (quoting the FDA's Guidance for Industry: E9 Statistical Principles for Clinical Trials, 26 (Sept. 1998) ("FDA 1998

[2] "¶__" refers to paragraph numbers in the CAC unless otherwise noted.

[3] All emphasis is added unless otherwise noted.

Guidance")). However, "[i]f unplanned interim analysis is conducted, ***the clinical study should explain why it was necessary and the degree to which blindness had to be broken, and provide an assessment of the potential magnitude of bias introduced and the impact on the interpretation of the results.***" *Id*.

According to FDA guidance, when multiplicity[4] is present, "***statistical adjustments . . . are appropriate***" to quantify its impact on the rate of false positive conclusions. ¶ 40 (citing FDA 1998 Guidance). Failure to make multiplicity adjustments could render statistically significant findings misleading, as the FDA counsels: "***Care should be taken when interpreting putative statistically significant findings when there is no multiplicity adjustment***." *Id*. Likewise, the European Agency for the Evaluation of Medicinal Products ("EMEA") has issued guidance acknowledging that "***[i]t is well known that the chance of spurious positive chance finding increases with the number of questions posed, if no actions are taken to protect against the inflation of false positive findings from multiple statistical tests***." ¶ 41 (citing EMEA, Points to Consider on Multiplicity Issues in Clinical Trials, 10 (September 19, 2002) ("EMEA Multiplicity Guidance")). The EMEA therefore insists upon "***statistical procedures planned to deal with, or to avoid, multiplicity,***" which should be "***fully detailed in the study protocol . . . to allow an assessment of their sustainability and appropriateness.***" *Id*.

Hypothesis generation[5] similarly poses the potential to distort a study's results if not properly taken into account in the statistical evaluation of those results. Indeed, industry experts note that the P-value for a data-generated hypothesis formulated during the collection and

[4] "Multiplicity" is the use of multiple tests to assess intervention effects (*i.e*., treatment control differences) across multiple outcomes (*i.e*. endpoints). ¶ 34.

[5] "Hypothesis generation" is a process in which hypotheses are formulated during the collection and analysis of a study's results. ¶ 42.

analysis of a study's results is less meaningful than the same P-value for a hypothesis formulated in advance of a study. ¶¶ 42-43 (citing Stephen B. Hulley, *et al*., *Designing Clinical Research,* 61 (3rd ed., 2007) ("Designing Clinical Research")); Warran S. Bower, MD, MPH, *et al.*, *Are All Significant P Values Created Equal? The Analogy Between Diagnostic Tests and Clinical Research*, J. of the Am, Med. Ass'n, Vol. 257, No. 18, 2462 (May 8, 1987)). Accordingly, these experts caution that "[s]ignificant P values for data-generated hypothesis that were not considered during the design of the study . . . should be viewed with interest but skepticism[.]" ¶ 44 (quoting Designing Clinical Research at 61).

As set forth more fully below, Keryx's Phase 2 trial of perifosine involved all three of these factors. *E.g*., ¶ 69. Yet, contrary to FDA guidance and other industry standards, Defendants admittedly failed to adjust the P-values to account for these factors when performing their statistical analysis of the Phase 2 perifosine data, thereby rendering such analysis effectively uninterpretable. *Id*. Nevertheless, without explaining to investors that their positive interpretation of the data ignored these factors, Defendants repeatedly assured investors that the Phase 2 results demonstrated the efficacy of perifosine in treating mCRC, and that they could expect similar results in Phase 3 of the clinical trial. *E.g*., ¶¶ 60, 70.

B. Keryx's Clinical Trial Of Perifosine

At the start of the alleged Class Period in June 2009, Keryx's financial viability was in free-fall: it had no drugs on the market or in a Phase 3 clinical trial after the failure of its drug Sulonex in a Phase 3 clinical trial in 2008; it had burned through 75% of its liquid assets in the latest fiscal year; it had fired its independent auditor, KPMG, after KPMG's issuance of a "going concern" warning in the Company's latest consolidated financial statements; and its stock price was so chronically depressed that it faced de-listing from the NASDAQ-CM on which it traded. ¶¶ 22-28. Keryx had only two drugs in its development pipeline, perifosine and Zerenex, with

perifosine scheduled to conclude its clinical testing (and ideally, be marketable) well before Zerenex. ¶ 28. With no commercial revenues, the Company's only source of operating capital was stock market investors; Keryx's financial survival depended on convincing investors to believe in the promise of perifosine's future results before the Company was de-listed.

Keryx was solely responsible for conducting the clinical trials of perifosine necessary to obtain regulatory approvals for marketing the drug in North America, and as such, Keryx controlled the Phase 2 clinical trial of perifosine that concluded in the first half of 2009. ¶ 31; ¶¶ 50-59. In June 2009, Defendants began touting the "highly statistically significant" efficacy results and "demonstrated clinical benefit" of perifosine for the treatment of mCRC that had purportedly been established in the recently completed Phase 2 trial. *E.g.*, ¶¶ 60, 77, 85-94. However, such statements gave a materially incomplete description of the how the Phase 2 trial data was interpreted. *E.g.*, ¶¶ 84, 95.

Specifically, in these statements, Keryx did not disclose numerous critical facts regarding the perifosine Phase 2 trial results. *First*, Keryx did not disclose that, during the Phase 2 trial, it had: (1) interposed numerous unplanned interim analyses and data comparisons; (2) effectively used the same data to both generate the trial hypothesis and confirm it; and (3) structured the trial in a fashion that injected issues of multiplicity into the results. ¶¶ 49, 66. *Second*, Keryx did not disclose that it did not adjust the statistical analysis of the Phase 2 perifosine trial results to account for the fact that it had interposed these three factors into the trial – despite the fact that FDA guidance and other industry standards confirm that, if not properly adjusted-for, the presence of any of these three factors can render the statistical interpretation of trial data all but impossible. *Id.* Nonetheless, without these necessary qualifying statements, Defendants repeated claims of perifosine's statistically significant efficacy and clinical benefit results in the

treatment of mCRC in a torrent of investor communications and medical conference presentations in 2009, 2010 and 2011.

Keryx ultimately conducted a Phase 3 perifosine trial beginning in 2010, the results of which were not released until April 2, 2012. ¶¶ 61-64, 75. Keryx's overzealous promotion of perifosine's prospects garnered regulatory notice in June 2011, when the FDA sent Keryx a sanction letter regarding statements that Keryx had published on its website touting perifosine's purported "demonstrated" "safety and clinical efficacy," which the FDA found created an "overwhelming misleading impression . . . that [perifosine] is safe and effective." ¶ 63.

In early October 2011, Keryx issued a press release regarding the publication of a clinical manuscript regarding the Phase 2 perifosine mCRC trial in an online edition of the Journal of Clinical Oncology (the "*JCO* manuscript"). ¶ 65. Keryx stated that the *JCO* manuscript "highlights the efficacy and safety data on the 38 mCRC patients participating in this Phase 2," including the "demonstrated statistical significance [of the perifosine treatment] with respect to median overall survival and median time to tumor progression," but also noted that the efficacy data from the Phase 2 study had been publicly available since June 2010. *Id.*

However, contrary to Keryx's representation, the clinical manuscript in question revealed technical information about the perifosine Phase 2 study that was new and highly material with regard to evaluating what the study data could actually be said to show. ¶ 66. In particular, for the first time, Keryx disclosed that it had relied on 25 of the study's 38 total participants to both generate the trial's hypothesis and confirm it, and that the Company had interposed multiple unplanned interim analyses and comparisons of the data during the course of Phase 2, but that it had not adjusted the P-values (or statistical metrics against which the study results were tested in

order to exclude randomness as a cause) to account for these unplanned analyses and comparisons. *Id.*

The market ultimately appreciated the import of this revelation days later on October 19, 2011, after a stock analyst published on the website *TheStreet.com* a non-technical explication of the *JCO* manuscript and a critical analysis of its implications that was based on the analyst's consultation with oncologist and University of Chicago professor Dr. Mark Ratain. ¶ 67. Dr. Ratain's critique explained that Keryx's failure to adjust the P-values that it applied to the perifosine Phase 2 data in light of the unplanned interim analyses, multiplicity, and hypothesis generation issues that Keryx had injected into the study meant that: (i) "the p values are not real p values" – the statistical analysis of the results was measured against an inappropriate and unfounded standard of significance; and (ii) the Phase 2 results were "un-interpretable." ¶ 67. This critique constituted a partial corrective disclosure of Keryx's misleading statements, and the Company's stock price fell by 6% in response. ¶ 148.

Keryx responded aggressively, including through a letter from Keryx's attorneys to the analyst who reported Dr. Ratain's analysis of the implications of the Phase 2 study, and through a parade of reassuring statements about the Company's confidence in the Phase 2 results, including the purportedly meaningful overall survival results, as a precursor to similar results in the Phase 3 perifosine trial. *E.g.*, ¶¶ 70-74, 127. The Company's statements between October 2011 and April 2012 glossed over and concealed the risk that the Phase 2 perifosine trial had not generated any statistically sound basis on which to proceed to the Phase 3 perifosine trial, or to expect that the Phase 3 trial would yield positive efficacy results. This risk materialized when Keryx revealed the awful Phase 3 results in April 2012. ¶ 75. The results showed that patients in the perifosine arm of the study survived an average of 6.4 months, while patients receiving a

placebo survived an average of 6.8 months – a result with a hazard ratio of 1.11, which meant that patients treated with perifosine had notably worse survival than patients that were not given the drug.[6] ¶ 75. This stunning result sent Keryx's stock price plummeting. *Id.*

III. Argument

A. Applicable Legal Standards

To survive a motion to dismiss under Fed. R. Civ. P. 12(b)(6), a complaint need only "allege a plausible set of facts sufficient 'to raise a right to relief above the speculative level.'" *SEC v. Gabelli*, 653 F.3d 49, 57 (2d Cir. 2011) (citation omitted). A complaint satisfies this standard if it sets forth "enough facts to state a claim to relief that is plausible on its face." *Starr v. Sony BMG Music Entm't*, 592 F.3d 314, 321 (2d Cir. 2010) (citation and internal quotation omitted). An alleged claim is facially plausible when it is supported by factual allegations that "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 663 (2009). In evaluating a dismissal motion, the court "must accept as true all of the factual allegations contained in the complaint" and construe the complaint in the light most favorable to the plaintiff. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 572 (2007) (citation and internal quotation omitted). Plaintiffs bringing claims under Section 10(b) of the Exchange Act must also satisfy (1) Fed. R. Civ. P. 9(b) by alleging with particularity the circumstances constituting the fraud, and (2) the PSLRA by setting forth facts giving rise to an inference that the defendant acted with scienter that is "cogent and at least as

[6] According to the National Cancer Institute, a hazard ratio is: "A measure of how often a particular event happens in one group compared to how often it happens in another group, over time. In cancer research, hazard ratios are often used in clinical trials to measure survival at any point in time in a group of patients who have been given a specific treatment compared to a control group given another treatment or a placebo. A hazard ratio of one means that there is no difference in survival between the two groups. A hazard ratio of greater than one or less than one means that survival was better in one of the groups." *See http://www.cancer.gov/dictionary?cdrid=618612.*

compelling as any opposing inference of nonfraudulent intent." *Tellabs v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 314 (2007).

B. False And Misleading Statements

Defendants' motion to dismiss strains to portray this case as a "nothing more than a copycat" of *Aeterna*. Def. Br. 1.[7] Not so. The CAC here contains comprehensive allegations of falsity, including the precise allegations that the court found to be lacking in *Aeterna*. Under the same analysis applied in *Aeterna*, Plaintiff adequately pleads falsity.

1. Plaintiff's Falsity Allegations Are Adequately Particularized

In accordance with Rule 9(b) and the PSLRA's heightened pleading requirements, Plaintiff pleads with particularity that Defendants made false and materially misleading statements. Defendants argue that Plaintiff's falsity allegations are insufficient under Rule 9(b) and the PSLRA because the CAC includes "large block quotations and conclusory boilerplate." Def. Br. 8. However, Defendants tellingly ignore not only Plaintiff's use of bolded and italicized text emphasizing the false and misleading portions of the block quotations, *see, e.g.*, ¶¶ 77, 85-90, 92-94, 96-98, 101-106, 109, 112-114, 124, 126-128, but also Plaintiff's allegations further identifying as false and misleading Defendants' statements relating to: (1) the statistical significance of the Phase 2 results (*e.g.*, ¶ 84); (2) the demonstrated efficacy of perifosine (*e.g.*, *id.*); (3) the purported P-values generated from the Phase 2 data (*e.g.*, ¶ 95); (4) the integrity of the Phase 2 study (*e.g.*, ¶ 123); and (5) the expectation of a positive result in the Phase 3 study (*e.g.*, ¶ 129).[8] Thus, Defendants' assertion that Plaintiff has failed to adequately specify each false and misleading statement is baseless.[9]

[7] References to "Def. Br. __" are to Defendants' Memorandum of Law in Support of Their Motion to Dismiss Plaintiff's Consolidated Amended Complaint (ECF No. 38).

[8] Defendants raise distracting red herring arguments disputing the CAC's falsity allegations with respect to other non-highlighted portions of the block quotations that the CAC plainly does not challenge as actionable

Further, Plaintiff outlines separately the precise factual basis for why each of these statements is materially misleading. In particular, Plaintiff alleges that Defendants failed to disclose that Keryx had interposed certain factors into its Phase 2 study that required Keryx to adjust the P-values applied to the Phase 2 data, but that Keryx failed to make such an adjustment to the P-values, which rendered Keryx's statistical analysis of the Phase 2 data uninterpretable. ¶¶ 49, 69, 84, 95, 116, 123, 129. Such allegations properly plead falsity with particularity. *See, e.g.*, *City of Providence v. Aeropostale, Inc.*, No. 11 Civ. 7132 (CM) (THK), 2013 U.S. Dist. LEXIS 44948, at *26 (S.D.N.Y. Mar. 25, 2013) (complaint will not be dismissed for failure to plead fraud with particularity where it "specifies each statement alleged to have been misleading, outlines separately the reasons why each statement is misleading, and where applicable, states with particularity all facts on which 'information or belief' is formed.") (citation omitted)).[10]

Defendants' contention that Plaintiff's consistent use of the same "boilerplate" explanation for why Defendants' repeated statements touting perifosine's Phase 2 results are false and misleading amounts to an "impermissible" and "faulty and fatal" pleading technique is belied by the case law. Def. Br. 9. Indeed, courts in this District have upheld this precise pleading method under Rule 9(b) and the PSLRA. *See*, *e.g.*, *Aeropostale,* 2013 U.S. Dist. LEXIS

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misrepresentations under Section 10(b). *See* Def. Br. 10 (citing ¶¶ 93, 97). These arguments are irrelevant and should be ignored.

[9] Indeed, the infirmities identified in *Tabor v. Bodison Biotech, Inc.*, where the plaintiffs failed to allege "exactly which statements" were false, 579 F. Supp. 2d 438, 452 (S.D.N.Y. 2008), and *In re Alcatel Securities Litigation*, where the plaintiffs "neglect[ed] to make it clear what portion of each quotation constitutes a false representation," 383 F. Supp. 2d 513, 534 (S.D.N.Y. 2005), are clearly absent here.

[10] The cases that Defendants rely upon do not warrant a different conclusion. Plaintiff's detailed explanation for why Defendants' statements are false and misleading bears no resemblance to the "generalized explanations" in *In re SINA Corp.*, No. 05 Civ. 2154(NRB), 2006 WL 2742048, *6 (S.D.N.Y. Sept. 26, 2006), or the "vague and conclusory" allegations in *Tabor*, 579 F. Supp. 2d at 453. Further, contrary to *Alcatel*, the CAC's falsity allegations do not amount to a "laundry list" that "plac[es] the burden on the Court to sort out the alleged misrepresentations and then match them with the corresponding adverse facts." *Alcatel*, 383 F. Supp. 2d at 534. Instead, the CAC bolds specific concise text that contains the false and misleading statements and omissions and specifically identifies why they are false.

44948, at *17 (falsity pleaded with particularity where complaint alleged the same reasons for why similar statements in separate press releases were false and misleading); *In re Alstom SA*, 406 F. Supp. 2d 433, 455 (S.D.N.Y. 2005) (plaintiffs' method of pleading, which repeated "boilerplate" explanation for why each statement was misleading, satisfied requirements of Rule 9(b)); *see also, e.g.*, *In re Tyco Int'l, Ltd.*, MDL 02-1335-B, 2004 WL 2348315, at *11 (D.N.H. Oct. 14, 2004) ("After identifying each specific misleading statement, the complaint refers readers to other sections that list multiple reasons why the statement is misleading. This is a reasonable way to address a complicated securities fraud case."). Plaintiff's falsity allegations thus satisfy Rule 9(b) and the PSLRA.[11]

2. Defendants Stated Misleading Half-Truths Regarding The "Statistically Significant" Efficacy And Clinical Benefit Of Perifosine In The Treatment Of mCRC

Throughout the Class Period, Defendants repeatedly touted to investors the "highly statistically significant" results of the Phase 2 mCRC perifosine trial, which purportedly demonstrated perifosine's "clinical benefit." ¶ 60. These statements amounted to misleading half-truths because Defendants omitted crucial facts that, if disclosed, would have raised serious questions concerning the accuracy of such statements. *See Gabelli*, 653 F.3d at 57 ("The law is well settled . . . that so-called 'half-truths' – literally true statements that create a materially misleading impression – will support claims for securities fraud."); *Fogarazzo v. Lehman Bros., Inc.*, 341 F. Supp. 2d 274, 294 (S.D.N.Y. 2004) ("A statement can also be misleading, though not

[11] Defendants' reliance upon *Rombach v. Chang* is likewise misplaced. There, the alleged misrepresentations were forward-looking statements protected by the PSLRA's safe-harbor provision. *See* 355 F.3d 164, 173 (2d Cir. 2004). As such, the plaintiffs were required to show that the company knew at the time it made such statements that the risks of its integration and liquidity problems had already transpired. *See id.* Finding that "the allegations in the complaint are consistent with unremarkable circumstances short of financial peril or instability," the Second Circuit concluded that the plaintiffs failed to allege falsity with particularity. *Id.* Defendants' statements in this case regarding perifosine's statistically significant Phase 2 results and demonstrated efficacy are not forward-looking. Thus, Plaintiff need not allege that Defendants knew upon making such statements that the risk of perifosine's failure had already transpired.

technically false, if it amounts to a half-truth by omitting some material fact."); *In re Immune Response Sec. Litig.*, 375 F. Supp. 2d 983, 1019 (S.D. Cal. 2005) (defendants' statements "publicly reporting [clinical trial] results that they knew or should have known were either so incomplete or so statistically flawed as to lack clinical significance" were materially misleading because they "portray[ed] the results of the clinical trial in an unduly optimistic light."). Specifically, Defendants failed to disclose that they did not adhere to FDA guidance and industry norms and adjust the P-values when evaluating the statistical significance of the Phase 2 results to account for the impact of multiplicity, unplanned interim analysis, and hypothesis generation on their statistical analysis. ¶¶ 49, 69, 84, 95, 116, 123, 129. Investors were entitled to know this highly material fact because Defendants' failure to make such adjustments to the P-values could render the statistical analysis of the Phase 2 results effectively uninterpretable. *Id.*[12] Accordingly, Defendants had no reasonable basis to claim that the Phase 2 results were "statistically significant," or that they demonstrated perifosine's "clinical benefit" without providing the full truth about the statistical analysis on which such claims rested. *Id.*

Defendants unpersuasively attempt to equate CAC's falsity allegations to the "generalized criticisms of the perifosine study" alleged in *Aeterna*. Def. Br. 10. In drawing this comparison, Defendants patently misconstrue the CAC's well-pleaded facts, none of which "go toward the design of the study." 2013 WL 2399869, at *10. Specifically, Defendants argue that Plaintiff fails to show falsity based upon mere criticisms of the perifosine study's use of multiple research arms and inclusion of the original 25 stage 1 patients in stage 2. Def. Br. 13, 16. This argument is baseless. In *Aeterna*, the plaintiffs alleged that the defendants' "use of multiple

[12] In particular, because the Phase 2 study involved unplanned interim analysis, Defendants should have explained "***why it was necessary and the degree to which blindness had to be broken, and provide an assessment of the potential magnitude of bias introduced and the impact on the interpretation of the results[,]"*** pursuant to governing FDA guidance. ¶ 45 (quoting FDA 1998 Guidance at 26).

research arms gave defendants several opportunities to identify a statistically significant benefit, and heightened the likelihood of finding a false positive." 2013 WL 2399869, at *9. The Court concluded that such allegations "merely amount to a competing view of how the trial should have been designed, not an allegation of material misstatement or omission." *Id*. at *10.

Here, by contrast, Plaintiff does not allege falsity based upon perceived "flaws" in the design or methodology of perifosine's clinical trial. Rather, Plaintiff alleges that Defendants' statements regarding purportedly "statistically significant" P-values demonstrating the clinical efficacy of perifosine provided investors with a materially incomplete and inaccurate impression regarding perifosine's Phase 2 results and its potential for success in Phase 3. In fact, Defendants failed to qualify such statements by not disclosing that Keryx's statistical analysis did not adhere to FDA guidance and industry norms by adjusting the P-values to account for the study's use of unplanned interim analyses, multiple research arms, and hypothesis-generated data. ¶¶ 49, 69, 84, 95, 116, 123, 129. Such materially misleading half-truths are clearly actionable. *See Gabelli*, 653 F.3d at 57; *Fogarazzo*, 341 F. Supp. at 294; *Immune Response*, 375 F. Supp. 2d at 1019.

Defendants further misapply the Court's reasoning in *Aeterna* to argue that Plaintiff's allegations regarding Keryx's unplanned interim analysis are not actionable. Def. Br. 15. In *Aeterna*, the plaintiffs alleged that the unplanned interim analysis during Phase 2 of the trial contradicted the defendants' statements characterizing the trial as "double-blind." 2013 WL 2399869, at *6. The Court determined that such allegations failed to plead a material misstatement because they did not aver "a generally accepted standard for conducting a double-blind study[,]" or "how the defendants' approach . . . . materially contravenes [the FDA's] guidance." *Id*. at *8. Here, in contrast, Plaintiff alleges that Defendants' statistical analysis

deviated from FDA guidance and industry standards, and that Defendants therefore had a duty to disclose this departure from industry standards in order to ensure that their statements concerning the purported "statistical significance" and "demonstrated efficacy" of perifosine's Phase 2 results were complete and accurate. *See In re Marsh & McLennan Cos. Sec. Litig.*, 501 F. Supp. 2d 452, 469 (S.D.N.Y. 2006) ("corporations have a duty to disclose all facts necessary to ensure the completeness and accuracy of their public statements"); *In re Synergen, Inc. Sec. Litig.*, 863 F. Supp. 1409, 1418 (D. Colo. 1994) ("[H]aving touted the Phase II results, the defendants may have had a duty to disclose known facts that would have placed the Phase II trial in a different light.").[13]

Finally, Defendants assert that, in any event, the presence of multiplicity and hypothesis generation was already disclosed by the Company from the outset in its publicly available synopsis of the Phase 2 protocol. Def. Br. 14, 16.[14] In addition, Defendants contend that the *JCO* manuscript disclosed the presence of multiplicity and unplanned interim analysis. Def. Br. 14, 15. These arguments miss the mark, as Plaintiff alleges that Defendants' statements were rendered false and misleading by their omission of Keryx's failure to adjust the P-values in its statistical analysis to account for the impact of these three factors. ¶¶ 49, 69, 84, 95, 116, 123, 129. As such, the Company's public disclosure of these factors in the protocol synopsis did not

[13] Defendants additionally assert that the CAC's allegations regarding hypothesis generation are deficient because, like the allegations in *Aeterna*, they do not point to any FDA guidance that required Keryx to abandon the original 25 patients used in stage 1. Def. Br. 16-17. Setting aside this argument's implicit charge that Plaintiff's falsity allegations are, at bottom, criticisms of Keryx's study design, which they are not, Plaintiff cites applicable FDA guidance recognizing that adjustments to P-values should be made whenever factors with the potential to impact statistical findings are present. ¶¶ 40, 45-48. As recognized by leading authorities in the field, hypothesis generation is one such factor. ¶¶ 42-44.

[14] Defendants argue that the statement in the protocol synopsis that "the initial study or component(s) of the study will be expanded" disclosed the presence of hypothesis generation. Def. Br. 16. However, this representation makes no mention of the fact that the expanded study would include the original 25 patients from whom data was collected to formulate the study's hypothesis. Moreover, this argument poses a question of fact that cannot properly be resolved at the pleading stage. *See Iqbal*, 556 U.S. at 678 (noting that the court must accept facts as true for purposes of a motion to dismiss).

alert investors to the material fact that the P-values used in Keryx's statistical analysis were uninterpretable, and therefore provided no reasonable basis for Defendants' statements regarding perifosine's "statistically significant" Phase 2 results and "demonstrated efficacy." *Id.*[15]

Having failed to show that the CAC's falsity allegations suffer from the same deficiencies identified in *Aeterna*, Defendants offer no other basis for dismissing the CAC on falsity grounds.[16] Accordingly, Plaintiff adequately pleads falsity based upon Defendants' omission of material facts rendering their statements misleading half-truths. *See Gabelli*, 653 F.3d at 57; *Fogarazzo*, 341 F. Supp. 2d at 294.

IV. The Defendants Acted With Scienter

A plaintiff can establish scienter by "alleging facts (1) showing that the defendant[] had both motive and opportunity to commit the fraud **or** (2) constituting strong circumstantial evidence of conscious misbehavior or recklessness." *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 99 (2d Cir. 2007).[17] In particular, recklessness may be pleaded through plausible allegations that the defendants "knew facts or had access to information suggesting that their

[15] As alleged in the CAC, while the *JCO* manuscript publicly disclosed that Keryx did not adjust the P-values in its analysis, it did so in highly technical language that was not understandable to reasonable investors. ¶¶ 66-67. Further, the *JCO* manuscript's disclosure of unplanned interim analysis did not absolve Defendants from ***"explain[ing] why it was necessary and the degree to which blindness had to be broken, and provid[ing] an assessment of the potential magnitude of bias introduced and the impact on the interpretation of the results."*** ¶ 45 (quoting FDA 1998 Guidance at 26). It was not until October 19, 2011 that investors became aware of the implications of Keryx's failure to adjust the P-values in its statistical analysis, as explained in Dr. Ratain's critique published on *TheStreet.com*. ¶ 67.

[16] As Plaintiff clearly does not allege that Defendants' statements were false and misleading due to "flaws" in the design or methodology of Keryx's clinical study, or the Company's "unsound" statistical analysis, the other cases relied upon by Defendants are similarly inapposite. *See Kleinman v. Elan Corp.*, 706 F. 3d 145, 154 (2d Cir. 2013) (plaintiff's criticisms of clinical study's methodology failed to assert actionable fraud claim); *In re MELA Scis., Inc. Sec. Litig.*, No. 10 CV 8774(VB), 2012 WL 4466604, *13 (S.D.N.Y. Sept. 19, 2012) (allegation of "unsound statistical analysis" in a clinical study does not support securities fraud claim); *In re Rigel Pharm., Inc. Sec. Litig.*, 697 F.3d 869, 879 (9th Cir. 2012) (plaintiff's mere criticism of statistical methodology employed by defendants does not adequately plead falsity).

[17] Defendants make the irrelevant argument that Plaintiff has failed to adequately plead scienter under a "motive and opportunity" framework. *See* Def. Br. 18-20. This straw man exercise serves only to distract from Plaintiff's straightforward allegations of Defendants' recklessness.

public statements were not accurate." *Novak v. Kasaks*, 216 F.3d 300, 311 (2d Cir. 2000); *In re Bank of Am. Corp. Sec., Deriv. & ERISA Litig.*, No. 09 MD 2058(PKC), 2011 WL 3211472, at *4 (S.D.N.Y. July 29, 2011).

The scienter analysis is holistic, and asks "whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter." *Tellabs*, 551 U.S. at 323. Factual allegations do not "require great specificity" in order to adequately plead scienter. *Ganino v. Citizens Utils. Co.*, 228 F.3d 154, 169 (2d Cir. 2000); *see also New Orleans Ems. Ret. Sys. v Celestica, Inc.*, 455 F. App'x 10, 15 (2d Cir. 2011). Moreover, the "strong inference" of scienter demanded under the PSLRA "need not be irrefutable, *i.e.*, of the 'smoking gun' genre, or even the most 'plausible of competing inferences.'" *Tellabs*, 551 U.S. at 324 (quotation omitted).

The CAC alleges with particularity that Defendants recklessly stated misleading half-truths and omitted material facts that they knew regarding the results of the Phase 2 perifosine trial. Indisputably, between June 2009 and October 2011, Defendants trumpeted the "highly statistically significant" efficacy results seen in the Phase 2 trial while hiding the fact that they had interposed into the trial – but failed to adjust for – numerous factors that materially impact the statistical analysis of the study data. *E.g.*, ¶¶ 3-5, 64, 77-83. Keryx's October 2011 *JCO* manuscript establishes beyond any doubt that Keryx determined (1) not to adjust the Phase 2 statistical analysis for the factors that it had interposed, and (2) not to reveal this fact for over two years. *E.g.*, ¶¶ 6, 65-66, 134, 136.

Similarly, Keryx's insistence after October 2011 that the Phase 2 efficacy results were "highly statistically significant" and provided a strong rationale for advancing to a Phase 3 trial, while it continued to withhold detailed information about the interim analyses and other distorting factors that it had injected into the Phase 2 trial, lacked any reasonable basis. ¶¶ 64,

93, 97-98.[18] Keryx's recklessness with respect to its Class Period misrepresentations is thus properly alleged. *See IBEW Local 90 Pension Fund v. Deutsche Bank AG*, No. 11 Civ. 4209(KBF), 2013 WL 1223844, at *13 (S.D.N.Y. Mar. 27, 2013) (scienter alleged as to defendants who knew information that rendered their statements materially inaccurate); *In re AIG 2008 Sec. Litig.*, 741 F. Supp. 2d 551, 533 (S.D.N.Y. 2010) (scienter alleged as to defendants who touted strength of risk controls despite knowledge of serious risk exposures and deficient controls).[19]

In their attempts to counter the CAC's recklessness allegations, Defendants mischaracterize the CAC. *First*, Defendants' contention that Plaintiff has not shown Defendants' "recklessness in adopting the statistical analysis chosen" is irrelevant, as it does not describe the theory of liability that Plaintiff advances. Plaintiff does not allege that Defendants recklessly designed or analyzed the perifosine study; instead, Plaintiff alleges that Defendants recklessly misrepresented the statistical significance of the Phase 2 results by not disclosing that they had interposed factors into the study that impacted the reliability of the statistical findings of the study data.

The regulatory guidelines and articles cited in the CAC show that the factors Defendants interposed are universally recognized to have a significant effect on the statistical analysis of study data. ¶¶ 35-49. As such, Defendants would have known that the presence of these factors – which Defendants did not disclose for years, and then downplayed and glossed over –

[18] For example, contrary to FDA guidance, Defendants still did not explain after October 2011 why the unplanned interim analysis in Phase 2 "***was necessary and the degree to which blindness had to be broken"***, nor did they ***"provide an assessment of the potential magnitude of bias introduced and the impact on the interpretation of the results."*** ¶ 45 (quoting FDA 1998 Guidance).

[19] *See also Gabelli*, 653 F.3d at 57 (noting that "[t]he law is well settled . . . that so-called 'half-truths'—literally true statements that create a materially misleading impression—will support claims for securities fraud" and finding intent adequately pleaded through allegations that the defendant knew or was reckless in not knowing that his statements were misleading where he controlled activity that rendered them misleading).

constituted important information about the conduct of the study, the purported statistical significance of its results, and the rationale it provided for the Phase 3 trial. Contrary to Defendants' assertion, therefore, the cited regulatory guidelines and literature "would have suggested" to Defendants "that their public statements were not accurate" or were "materially misleading." Def. Br. 21.

Second, Defendants appear to suggest that the CAC lacks allegations specifying what material information Defendants possessed about the misrepresented "true facts" concerning the Phase 2 trial. This is nonsense. As alleged, Defendants controlled and knew all there was to know about the Phase 2 trial and dictated what was published about it and when. *E.g.*, ¶¶ 3, 6, 31, 51, 55-57, 66-67, 134, 136. It is telling that Defendants avoid reference to the *Aeterna* action in their scienter argument. There, the court rejected allegations that Aeterna – Keryx's partner in developing perifosine – had scienter with respect to allegedly undisclosed facts about the Phase 2 trial because there were no allegations that Aeterna "received information" or "guided results" in the trial; rather, the facts alleged made clear that "Keryx was responsible for all major aspects of the design and execution of the perifosine trials." *Aeterna*, 2013 WL 23998969, at *19 (noting factual allegations that "Keryx was conducting the research;" "Keryx—not [Aeterna]—presented the initial, allegedly misleading Phase 2 results to the American Society of Clinical Oncology" and reported the "statistically significant benefit in survival" purportedly seen in Phase 2).

In sum, that it was Keryx's decision to (1) interpose the factors at issue into the Phase 2 trial, but (2) not adjust the statistical analysis accordingly, is beyond dispute. Defendants' recklessness in not disclosing these material facts is therefore properly alleged.[20]

[20] The Second Circuit's standard for pleading scienter does not require Plaintiff to allege both recklessness and motive and opportunity. *See*, e.*g.*, *SEC v. U.S. Envtl., Inc.*, 155 F.3d 107, 112 (2d Cir. 1998) (allegations of recklessness are sufficient to establish scienter). In further support of the CAC's scienter allegations, however, Plaintiff also alleges that Bentsur was motivated to commit fraud by his need to instill public confidence in the

V. Plaintiff Has Adequately Pleaded Loss Causation

Defendants' argument that Plaintiff has failed to plead loss causation lacks merit. "The pleading of loss causation – even for securities fraud claims – is governed by Rule 8 notice pleading standards . . . ." *Bricklayers & Masons Local Union No. 5 Ohio Pension Fund v. Transocean Ltd.*, 866 F. Supp. 2d 223, 245 (S.D.N.Y. 2012). Under these standards, Plaintiff's "complaint need only provide the defendant with 'some indication of the loss and the causal connection that the plaintiff has in mind.'" *Id.* (quoting *Dura Pharms, Inc. v. Broudo*, 544 U.S. 336, 347 (2005)). It does so. ¶¶ 148-52.

In their loss causation arguments, Defendants again resort to mischaracterizations of the CAC. Plaintiff quite clearly alleges that one partial corrective disclosure occurred on October 19, 2011. ¶ 148. In that disclosure, an oncologist and medical school professor provided an original, critical analysis of the highly technical online *JCO* manuscript for a stock analyst. He did not simply repeat what the *JCO* manuscript stated, but analyzed its implications – in particular with respect to the purported statistical significance of the Phase 2 trial – and drew conclusions ***directly contrary*** to what Defendants and the article had asserted about the statistical analysis of the Phase 2 results. *See* ¶ 117 (Keryx press release stating that *JCO* manuscript showed "statistical significance" of perifosine's efficacy data). Such an original report and analysis can serve as a corrective disclosure. *See Billhofer v. Flamel Techs., S.A.*, 281 F.R.D. 150 (S.D.N.Y. 2012) (finding at class certification that stock analyst research report on clinical

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Company's development of perifosine in order to buy time until the pending completion of the Company's Phase 3 study of Zerenex, which was poised to achieve positive results. ¶ 137.

results that had appeared "in an obscure location on the internet" ten days earlier could serve as a corrective disclosure).[21]

Plaintiff also pleads loss causation as to April 2, 2012, under the "materialization of the risk" theory, through allegations that Defendants' misstatements "conceal[ed] a condition or event which then occur[red] and cause[d] the plaintiff's loss." *Hunt v. Enzo Biochem, Inc.*, 530 F. Supp. 2d 580, 594 (S.D.N.Y. 2008); *accord Lentell v. Merrill Lynch & Co.*, 396 F.3d 161 (2d Cir. 2005). Under such theory of loss causation, the "revealing events" through which the concealed risk "comes to light" need "not identify prior company statements as misleading, but they must reveal new information previously concealed and fall within the 'zone of risk' concealed so that the events were foreseeable consequences of the fraud." *Liberty Media Corp. v. Vivendi Universal, S.A.*, 923 F. Supp. 2d 511, 516-17 (S.D.N.Y. 2013) (quoting *In re Vivendi Universal, S.A. Sec. Litig.*, 765 F. Supp. 2d 512, 555 (S.D.N.Y. 2011)).

The concealed risk here was that Defendants' claims regarding the "highly statistically significant" efficacy results of the Phase 2 perifosine trial in fact lacked a sound basis, and that there was no better than a random chance that perifosine would actually demonstrate an efficacy benefit in a Phase 3 trial. Contrary to Defendants' argument, this is precisely the material fact that "the Company misrepresented and/or omitted material facts with respect to the Phase 3 trial," and which materialized in that trial's results. Def. Br. 24. Thus, Plaintiff has adequately pleaded "that the zone of risk – a [failure in the Phase 3 trial] – would have been thought unlikely by shareholders who believed [Keryx's] repeated assurances about" the highly

[21] *In re Omnicom Group*, 597 F.3d 501 (2d Cir. 2010), does not compel a different conclusion. There, the Second Circuit rejected plaintiffs' allegations of loss causation based on a mere "negative journalistic characterization of previously disclosed facts." *Id.* at 512. Here, in contrast, Plaintiff alleges loss causation based on an original, specialized analysis of information in the *JCO* manuscript that drew conclusions which fundamentally diverged from the analysis of the same information Defendants had published two weeks earlier.

statistically significant efficacy results of the Phase 2 trial. *Liberty Media*, 923 F. Supp. 2d at 528.

VI. Plaintiff Adequately Alleges A Claim Under Section 20(a)

As set forth above, Plaintiff adequately states a claim under Section 10(b). Defendants do not contest, and therefore concede, the other elements of Plaintiff's control-person claim. *See* Def. Br. 25 n.6. Accordingly, there is no basis to dismiss Plaintiff's Section 20(a) claim. *See In re Bank of Am. Corp. Sec., Derivative, & ERISA Litig.*, 757 F. Supp. 2d 260, 331-332 (S.D.N.Y. 2010) ("Defendants' argument is based solely on the necessity of a primary violation in order to proceed with a section 20(a) claim . . . . To the extent that the [] Complaint adequately pleads a primary violation, defendants' motion to dismiss [the section 20(a) claim] is denied.").

VII. Conclusion

For all of the foregoing reasons, Plaintiff respectfully requests that the Court deny Defendants' Motion in its entirety. If the Court perceives any portion of the CAC to be insufficient, Plaintiff respectfully requests leave to amend to cure any noted deficiencies pursuant to Rule 15(a)(2).

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